

## **REMARKS**

Claims 1-74 are pending in the application. Claims 1 and 71 have been amended and claims 42-70 have been withdrawn pursuant to a restriction requirement. No new matter has been introduced by the amendment.

### **Claim Objections**

An objection has been raised to claims 71-74 for use of the abbreviated forms for the recited bacteria. This objection is addressed by the amendment of claim 71 in which the full name of each bacteria has been spelled out in italicized form followed by the abbreviated form in parenthesis.

### **Rejection Under 35 U.S.C. § 112**

Claims 1-41 and 71-74 have been rejected for an alleged failure to provide support for claims reciting particular Magnolia Bark extract concentration in the oral cavity of a user. This rejection is overcome in view of the accompanying Declaration of Minmin Tian together with the following remarks.

The Applicants respectfully assert that one skilled in the art can readily determine the amount of the various ingredients of an edible film that are delivered to the oral cavity of a user from the information provided in the Applicants' specification. In the accompanying Declaration, Dr. Tian has determined the amount of ingredients delivered to the oral cavity per dosage, for both an example of a pullulan-free edible film according to the instant invention, and for an composition example provided by Sherl et. al. (Tian Declaration, paras. 6 and 11). Accordingly, the Applicants respectfully assert that one skilled in the art would not be required to perform undue experimentation in order to realize the claimed subject matter based upon the Applicants' specification. To the contrary, the claimed subject matter is readily determinable, as demonstrated by Dr. Tian in his accompanying Declaration. The Applicants further respectfully assert that the instant Office Action does not present evidence as to why a person skilled in the art would not be able to make and use the invention defined by the claims from the Applicants' disclosure. (MPEP §2163.04). Accordingly, the Applicants assert that the rejection should be withdrawn.

**Rejection Under 35 U.S.C. § 112, second paragraph**

Claims 1-41 and 71-74 have been rejected for ambiguity with respect to the identity of the particular component that relates to the recited concentration. This rejection is overcome in view of the amendment of claims 1 and 71 together with the following remarks.

Claims 1 and 71 have been amended to recite that the composition provides a concentration of Magnolia Bark extract having the specified concentration. The Applicants assert that the amendment removes any potential ambiguity regarding the identity of the component to which the specified concentration is directed.

**Rejection Under 35 U.S.C. § 103(a)**

Claims 1-41 and 71-74 have been rejected over Barkalow et al. in view of Nanba et al. and/or Sherl et al. These claims have also been rejected over Zyck et al. in view of Nanba and/or Sherl et al. These rejections are overcome in view of the accompanying Declaration of Minmin Tian together with the following remarks.

The Applicants respectfully assert that a *prima facie* case of obviousness has not been established in the instant Office Action. The Applicants assert that one skilled in the art would not be motivated to combine the teachings of a pullulan-free edible film as disclosed by Barkalow et al. with the dentifrices disclosed by Sherl et al. and Nanba et al. This is at least because those skilled in the art would not be motivated to combine Magnolia Bark extract in an amount that would provide the recited low concentration levels with a pullulan-free edible film. As pointed out by Dr. Tian in paragraph 8 of his Declaration, those skilled in the art consider pullulan to be a necessary ingredient in order to obtain germ kill authenticity with low concentration of antimicrobial agent in an edible film. Dr. Tian further points out at paragraph 11 of his Declaration that even in combination with Triclosan, the amount of Magnolia Bark extract in the formulation disclosed by Sherl et al. contains 14 times more Magnolia Bark extract than the Applicants' invention. Dr. Tian further points out that the efficacy achieved by the Applicants' pullulan-free edible film is surprising given the understanding of those skilled in the art regarding the role of pullulan in an edible film.

As demonstrated by the testing described in paragraphs 6 and 7 of Dr. Tian's Declaration, the Applicants' invention has shown germ-kill efficacy with extremely low concentrations of Magnolia Bark extract in a pullulan-free edible film. In particular, as described in paragraph 6 of Dr. Tian's Declaration, a dosage in the amount of .21 milligrams was found to reduce total bacteria counts in a clinical trial by 49 percent 20 minutes after consumption and 34 percent at 40 minutes after consumption. In paragraph 9 of his Declaration reproduced below, Dr. Tian concludes that these results are unexpected.

In view of the general understanding of the action of pullulan in edible films, I find it surprising that, in the invention of the '671 application, a pullulan-free combination of sodium alginate, maltodextrin, carrageenan, micro-crystalline cellulose, and a low amount of MBE, provide effective germ-kill against bacteria that cause bad breath. In the invention described in the '671 application, the amount of MBE delivered to oral cavity is below 1 microgram. This amount of antimicrobial agent is much less than would be expected necessary in a pullulan-free edible film that was effective at killing germs causing bad breath.  
(Declaration of Minmin Tian, para. 9).

Accordingly, the Applicants assert that they have provided evidence of unexpected results with their pullulan-free edible film composition.

The Applicants assert that a *prima facie* case of obviousness requires that there must be a reasonable expectation of success. (MPEP §2142). The Applicants have presented evidence that the combined teachings of the cited references do not establish a reasonable expectation of success. Further the Applicants assert that obviousness must be considered in view of all of the facts established by rebuttal evidence, and this evidence must be evaluated in consideration of the obviousness rejection. Moreover, the teaching or suggestion to combine the references and the reasonable expectation of success must be found in the prior art and not in the Applicants' disclosure. (MPEP §2143).

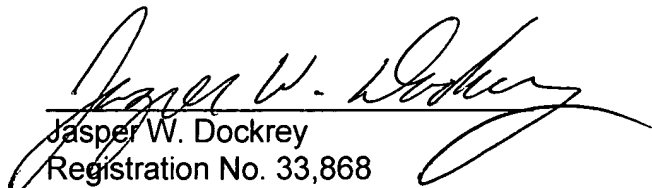
The Applicants assert that one skilled in the art would not be motivated to combine the teachings of the edible film as disclosed by Zyck et al. with the dentifrices disclosed by Sherl et al. and Nanba et al. This is at least because those skilled in the art would not be motivated to combine Magnolia Bark extract in an amount that would

provide the recited low concentration levels with the edible film disclosed by Zyck et al. The Applicants' foregoing remarks pertaining to Barkalow et al. are incorporated herein. The Applicants further assert that Zyck et al. qualifies as a prior art reference under 25 U.S.C. §102(e). As indicated on the face of Zyck et al., this reference and the instant application belong to the same assignee, Wm. Wrigley Jr. Company. The Applicants assert that Zyck et al. should be removed under 35 U.S.C. § 103(c), because the subject matter of Zyck et al. and the claimed invention were, at the time the invention was made, owned by the same person.

Through their submission of Declarations by Dr. Tian and Dr. Dodds, the Applicants have established substantial evidence of non-obviousness. The Applicants assert that this evidence clearly establishes that a combination of the cited references does not render the Applicants obvious. The Applicants are first to develop a pullulan-free edible film having the recited concentration levels. Further, the Applicants have established the efficacy of their claimed composition despite the belief of those skilled in the art that pullulan was a necessary component to achieve an effective edible film having a very low concentration of antimicrobial agent.

The Applicants have made a novel and non-obvious contribution to the art of edible film composition. The claims as issue distinguish over the cited references and are in condition for allowance. Accordingly, such allowance is now earnestly requested.

Respectfully submitted,

  
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